## REMARKS

### I. Status of the Application

Claims 1-13 and 15-17 are presently pending in the application. Claim 14 has been previously cancelled. Claims 1-13 and 15-17 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Claims 1-13 and 15-17 also stand rejected under 35 U.S.C. § 102(e) as being anticipated by Niederauer et al. (USPN 6,344,496, hereinafter "Niederauer"). Applicants respectfully request reconsideration of the pending claims in view of the foregoing amendments and the following remarks.

Applicants have amended the pending claims to more clearly define and distinctly characterize Applicants' novel invention. Specifically, independent claim 1 has been amended to delete "flexible and rigid" language and the "porous surface and nonporous core" limitation. Claim 1 has also been amended to recite a plasticizer dispersed within the rigid matrix only at the surface of the implant. Support for this amendment is implicit in the specification as filed, for example, Applicants' specification teaches soaking the implant for only 30 or 40 seconds (see Examples 1, 3, and 4), so one of skill in the art would instantly appreciate that the plasticizer would only have time to diffuse into the surface of the implant. The minimal contact time of the implant with the plasticizer simply would not be sufficient to allow the plasticizer to diffuse deeper than the surface of the implant, certainly not to the core of the implant. Indeed, plasticizer dispersed within only the surface of the implant is an inherent physical characteristic and a necessary result of implants made by one of skill in the art guided by the teachings of Applicants' specification. Since plasticizer is dispersed within only the surface of the implant, exit of plasticizer from the implant creates a porous surface, leaving a non-porous core. This is evidenced by the declaration of co-inventor Eija Pirhonen, filed on June 21, 2007.

Independent claim 2 has been amended to delete four limitations and to reword for clarity. Claim 4 has been amended to recite the NMP limitation deleted from claim 2, and delete the redundant porous limitation. Claims 9 and 10 have been amended to delete the "flexible and rigid" limitation. Claim 10 has been amended to clarify that the plasticizer is dispersed within the rigid matrix only at the surface of the implant, and that the implant, after insertion into the organ system, has a plasticizer-created porous surface and a substantially nonporous core. Support for these amendments can be found throughout the specification as filed, for example, as described above for the amendment to claim 2 (and in the declaration of co-inventor Eija Pirhonen, filed on June 21, 2007), and at page 4, lines 29-31 and at page 5, lines 10-13.

The amendments presented herein add no new matter. Applicants respectfully request entry and consideration of the foregoing amendments and reconsideration of the application in view of the following remarks, which are intended to place this case in condition for allowance.

## II. Claims 1-13 and 15-17 Are Definite

At page 2, section 3 of the instant Office Action, claims 1-13 and 15-17 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner is of the opinion that the subject claims are drawn to two separate inventions that cannot exist simultaneously: one being an implant comprising a matrix with plasticizer dispersed in the matrix, and the other being an implant with a plasticizer-created porous surface and a nonporous core. The Examiner is also of the opinion that the terms "flexible and rigid" in claims 1, 2, 9, and 10 are merely relative terms not defined by the claims or the specification. Applicants respectfully traverse the rejection.

An object of the claimed invention is to provide an implant that is easy to shape prior to implantation, yet has sufficient rigidity to support or attach tissue once implanted (e.g., specification page 5, paragraph [0017]). To this end, the claims are drawn to an implant having varying physical properties under different conditions. For example, the bending resistance of the implant prior to the insertion of the implant into an organ system (i.e., implantation) is substantially lower than after its insertion into the organ system (e.g., claims 1 and 2). The rigidity of the implant increases substantially after the implant is inserted into the organ system (e.g., claims 9 and 10). The decreased bending resistance prior to implantation is provided by a plasticizer dispersed within the rigid matrix of the implant. Once the implant is implanted, the plasticizer exits the implant so that the rigidity of the implant is substantially increased. Advantageously, the exit of plasticizer from the implanted implant creates a porous surface on the implant which serves as a structure to guide tissue regeneration and aids the attachment of tissue to the implant (e.g., specification page 5, paragraph [0017]). So the implant before and after insertion into an organ system are so related to each other as to be two embodiments of the same invention, not two separate and discreet inventions.

Nevertheless, Applicants have amended the subject claims to clarify the claimed subject matter. Claim 1 and its dependent claims are now directed to an implant comprising a rigid biodegradable polymer or copolymer matrix and a plasticizer dispersed within the rigid matrix only at the surface of the implant, whereas claim 2 is now directed to an implant comprising a rigid biodegradable polymer or copolymer matrix and a plasticizer-created porous surface and a substantially nonporous core. Claims 9 and 10 have been amended to clarify that the recited methods for manufacturing a biodegradable implant are such that the implant, after insertion into an organ system, has a plasticizer-created porous surface and a substantially nonporous core.

Thus, the amended claims do not recite an implant that comprises simultaneously both plasticizer dispersed within its rigid matrix only at the surface of the implant and a plasticizer-created porous surface. In addition, Applicants have deleted the terms "flexible and rigid" from the amended claims.

For at least the foregoing reasons, the claims are definite. Accordingly, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. §112, second paragraph, rejection and allowance of claims 1-13 and 15-17.

## III. Claims 1-13 and 15-17 Are Novel over Niederauer

At page 4, section 7 of the instant Office Action, claims 1-13 and 15-17 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Niederauer. Applicants respectfully traverse the rejection. Applicants submit that in order for a reference to anticipate the claims, it must disclose each and every limitation of the claims.

Applicants' claimed invention is directed in part to a biodegradable implant prior to implantation, comprising a rigid biodegradable polymer or copolymer matrix, and a plasticizer dispersed within the rigid matrix only at the surface of the implant; wherein the plasticizer is operative to substantially exit from the implant after coming into contact with tissue fluids of an organ system, wherein the bending resistance of the implant prior to the insertion of the implant into the organ system is substantially lower than after its insertion into the organ system. The claimed invention is also directed to an embodiment of the biodegradable implant after implantation, comprising a rigid biodegradable polymer or copolymer matrix, and a plasticizer-created porous surface and a substantially nonporous core. In addition, the subject claims are directed to methods for manufacturing such biodegradable implants.

Niederauer fails to disclose, teach or suggest each and every limitation of Applicants' claimed invention. Specifically, Niederauer fails to disclose an implant that has a plasticizer-created porous surface and a substantially nonporous core. Niederauer repeatedly teaches that its implant materials are either porous throughout or nonporous throughout (see col. 8, lines 4-11, col. 9, lines 1-5, and Examples 1 and 2). Furthermore, Niederauer fails to disclose an implant that has a plasticizer dispersed within its rigid matrix only at the surface of the implant. Nor does Niederauer disclose methods for manufacturing such implants having a plasticizer dispersed within its rigid matrix only at the surface of the implant, or a plasticizer-created porous surface and a substantially nonporous core.

The Examiner may wish to argue that these teachings are inherent in Niederauer at col. 9, lines 44-54, which discloses the incorporation of plasticizer into a biodegradable film. But this is not the case. In order to rely on an inherency argument, the Examiner must demonstrate that an implant having a plasticizer dispersed within its rigid matrix only at the surface of the implant or a plasticizer-created porous surface and a substantially nonporous core are "necessarily present" in the biodegradable film of Niederauer. To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

Applicants teach immersion of the implant in plasticizer (e.g., NMP) for a short period of time (e.g., 30-40 seconds) (see Examples 1, 3, 4), which necessarily results in plasticizer dispersed within the matrix of the implant only at its surface, since plasticizer is not given enough time to penetrate all the way to the core of the implant. Exit of plasticizer from the surface of Applicants' implant results in a plasticizer-created porous surface and a substantially

nonporous core. Niederauer does not specify a time period for immersion of its film in plasticizer, saying only that it should be immersed until as soft as desired (col. 9, lines 52-54). So this time period can be long enough for plasticizer to penetrate into the core of Niederauer's film. Indeed, Niederauer suggests to the skilled artisan that plasticizer is incorporated into the core of its film by teaching that a co-solvent should be mixed with the plasticizer to prevent complete dissolution of the polymer which makes up the film (col. 9, lines 47-52). The film would not be in danger of completely dissolving in plasticizer if the plasticizer is incorporated only in its surface, and does not penetrate into its core. Therefore, an implant having a plasticizer dispersed within its rigid matrix only at the surface of the implant is not "necessarily present" in Niederauer. Since plasticizer in only the surface of the implant is required to produce a plasticizer-created porous surface and a nonporous core, then an implant having a plasticizer-created porous surface and the nonporous core are not "necessarily present" in Niederauer either. Therefore, Niederauer does not inherently disclose these claim limitations.

For at least the foregoing reasons, Niederauer fails to disclose each and every limitation of the subject claims and so fails to anticipate the claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 102(e) rejection and allowance of claims 1-13 and 15-17.

## IV. CONCLUSION

Having addressed all outstanding issues, Applicants respectfully request entry and consideration of the foregoing amendments and reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

Respectfully submitted,

Date: January 16, 2008

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